RESEARCH PAPER

Potential reduced exposure products (PREPs) in industry trial testimony

Geoffrey Ferris Wayne

Tobacco Control 2006;**15**(Suppl IV):iv90–iv97. doi: 10.1136/tc.2004.009787

Correspondence to:
Geoffrey Ferris Wayne,
PO Box 183, Albion, CA
95410, USA;
ferriswayne@gmail.com

Received 20 August 2004
Accepted 13 January 2006

Objective: To identify patterns in trial testimony that may reflect on the intentions or expectations of tobacco manufacturers with regard to the introduction of potential reduced exposure products (PREPs).
Design: Research was conducted using the Deposition and Trial Testimony Archive (DATTA) collection of trial testimony and depositions housed online at Tobacco Documents Online (www.tobaccodocuments.org). Relevant testimony was identified through full-text searches of terms indicating PREPs or harm reduction strategies. The role and function of PREPs in testimony were classified according to common and contrasting themes. These were analysed in the context of broader trial arguments and against changes in time period and the market.
Results: Analysis of testimony suggests that the failure of PREPs in the market tempered initial industry enthusiasm and made protection of the conventional cigarette market its major priority. The ''breakthrough'' character of PREPs has been de-emphasised, with trial arguments instead positioning PREPs as simply another choice for consumers. This framework legitimises the sale of conventional brands, and shifts the responsibility for adoption of safer products from the manufacturer to the consumer. Likewise, testimony has abandoned earlier dramatic health claims made with regard to PREPs, which had undermined industry arguments regarding efforts to reduce harm in conventional products. More recent testimony advocates the broad acceptance of independent guidelines that would validate use of health claims and enable the industry to market PREPs to consumers.
Conclusion: Trial testimony reflects the changing role and positioning of PREPs by the tobacco industry. The findings are of particular importance with regard to future evaluation and potential regulation of reduced harm products.

Government and public health experts have long advocated the development of less harmful cigarettes to reduce the health toll of smoking.[1–3] In the 1970s, tobacco industry response to this strategy resulted in the introduction and intensive marketing of low yield or ''light'' cigarettes,[4] which demonstrated reduced smoke delivery as measured by the Federal Trade Commission (FTC) smoking assay. Both the Surgeon General and health care providers recommended ''lights'' for persons that could not quit,[5] and the majority of consumers today continue to believe that these products are safer.[6] Yet it has become clear that ''light'' cigarettes have failed to address negative health outcomes[7 8] and may in fact have persuaded some consumers not to quit.[9] Internal evidence indicates that manufacturers knew ''light'' cigarettes were not safer, despite marketing claims.[10–12]

More recently, a range of new products employing unconventional technologies and promising reduced health risks are being introduced into test markets. These products are commonly referred to as potential reduced exposure products, or PREPs. Some of the PREPs currently available include modified cigarettes such as Advance (Brown & Williamson), Quest (Vector), Omni (Vector) and Marlboro UltraSmooth (Philip Morris (PM)), as well as cigarette-like devices such as Eclipse (RJ Reynolds (RJR)) and Accord (PM) (fig 1). PREPs represent a range of harm reduction strategies including selective smoke delivery (for example, charcoal filtration, elimination of tobacco specific nitrosamines (TSNA)), reduced or eliminated nicotine delivery, and reduced toxicity or mutagenicity of smoke (for example, by heating rather than burning tobacco). The potential health impact of PREPs has made them an emerging priority among government and health agencies.[13]

Industry advertising and press claims have drawn on both published and unpublished findings to suggest that PREPs are less harmful than conventional products.[14–17] However, the reliability of industry studies has been called into question.[18] Further, most PREPs have not been subject to any impartial assessment of relative risk.[13 19] In its influential 2001 monograph, the Institute of Medicine (IOM) of the National Academy of Science evaluated the issue of tobacco harm reduction and concluded that there are no PREPs currently proven to be safer than conventional cigarettes.[19] However, the study indicated sufficient laboratory and human data to suggest that harm reduction is a feasible strategy to improve tobacco-related health outcomes, and might present an achievable goal for persons who cannot stop smoking.

Recent findings suggest that claims made by manufacturers may lead consumers to perceive PREPs as safer despite a lack of adequate evidence.[20] The introduction and marketing of PREPs may also prompt some consumers to delay quitting or some former smokers to resume tobacco use.[19 20] The IOM report emphasised the need to prevent widespread misperceptions about PREPs (and, by association, tobacco products in general), which might undermine tobacco control efforts known to reduce tobacco use. The lack of a reliable public source for information on the design and function of PREPs has proved a stumbling block for accurate assessment of their health impact.

Abbreviations: DATTA, Deposition and Trial Testimony Archive; FTC, Federal Trade Commission; IOM, Institute of Medicine; PM, Philip Morris; PREPs, potential reduced exposure products; R&D, research and development; RJR, RJ Reynolds; TSNA, tobacco specific nitrosamines

Figure 1 Some of the potential reduced exposure products, or PREPs, introduced in the US market.

One area that has yet to be examined is the role of PREPs within tobacco trial testimony (see Davis *et al*[21] in this journal supplement). There are significant challenges in attempting to draw conclusions about the intentions or expectations of the tobacco manufacturer based on statements made by individuals in a trial context. Not least of these is the trial context itself, in which the manufacturer is by definition presenting a case to explain, defend, promote, or minimise its own actions. Further, as the context of each particular trial shifts, the goals of the manufacturer may alternate as well, with testimony presumed to follow. To add to this complexity, the testimony reflects the differences inherent in statements made by different individuals, from different companies, with different backgrounds and opinions; and made in response to specific questions, and across time periods. Despite these challenges, the trial testimony presents a potentially valuable prism through which to consider tobacco industry strategies.

The goal of this study was to provide an assessment of the patterns apparent in the characterisation and discussion of PREPs in presentations made to jury during trial litigation. A sample of trial testimony focusing on PREPs was examined according to the hypothesis that this testimony may shed new light on the intentions, beliefs, and actions of manufacturers with regard to harm reduction products. The questions posed in the analysis of testimony were:

- What role or function do PREPs play within industry testimony?
- How are PREPs described within industry testimony?
- How has the role or description of PREPs changed in testimony over time (particularly in relation to corresponding changes in public positions, market introductions, or other significant events)?

The third question is especially relevant given that the available trial testimony coincides with the period of most significant activity for PREPs within the commercial marketplace (fig 2).

METHODS

Research was conducted using the Deposition and Trial Testimony Archive (DATTA) collection of trial testimony and depositions housed online at Tobacco Documents Online (www.tobaccodocuments.org/datta/). Relevant documents were identified using the online interface through full-text word searches of the DATTA collections. The searches consisted of terms indicating harm reduction, names of PREP brands on the market, and internal projects related to PREP development (listed in turn below):

- unconventional, non-conventional, reduced harm, harm reduction, reduced exposure, safe cigarette, safer cigarette, denicotinised, nicotine free
- Eclipse, Premier, Accord, Omni, Advance, Quest, Score, Next
- Delta, Sigma, Beta, Table, Trump, Tempo, ART.

Findings were limited to defence trial testimony and attorney statements, and excluded testimony and statements before the introduction of Eclipse in 1996 due to the limited number of statements identified. It should be noted that trial statements differ significantly in character from witness testimony, which is given under oath and in response to direct questions. Relevance was determined based on whether the testimony or statements described harm reduction generally, or specific PREP products, including internal PREP development, internal evaluation of PREPs, the role of PREPs in the marketplace, or other insight into PREP design

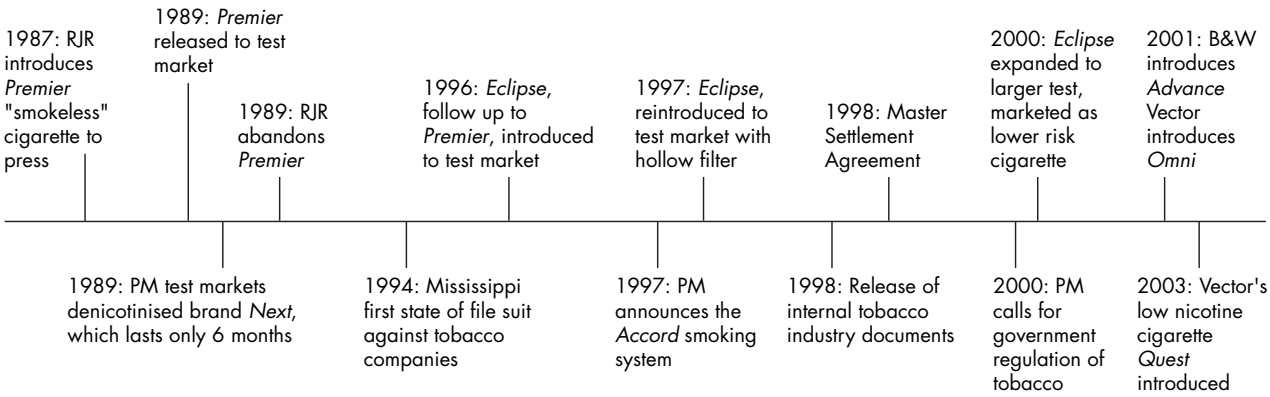

Figure 2 Timeline of introduction and marketing of potential reduced exposure products (PREPs). B&W, Brown & Williamson; PM, Philip Morris; RJR, RJ Reynolds

and function. Discussion of conventional harm reduction strategies (for example, selective filtration or smokeless tobacco) was excluded. Overall, 96 relevant ''segments'' were identified from direct testimony, cross examination, and attorney opening/closing statements. The selected testimony and statements ranged between the years 1996–2003, spanning 30 different trials, drawn from 23 separate witnesses as well as 12 attorneys, and totalling more than 250 000 words.

An initial analysis was conducted summarising the major points or arguments made in each segment of relevant witness testimony, and categorising these points according to a series of research questions: comparison of PREPs to conventional products; stated goals or objectives regarding PREPs; evaluations of market success/failure; reasons for market success/failure; plans for future product commercialisation; discussion of PREP safety; communicating benefits to consumers; technical descriptions or demonstrations; costs/efforts in internal development. Within each of these categories, both common and divergent themes were identified. Separately, the relevant primary arguments presented by trial lawyers in opening statements for both the plaintiffs and defendants for the 30 trials sampled in this study were identified and categorised as follows: feasibility of (or lack of) product alternatives; defective product design; reasonable response to health hazards/development of safer products; contribution to the science (versus fraudulent/irrelevant research); informing (or misinforming) consumers; and product use as choice. The themes identified within witness testimony were considered in relation to these primary trial arguments, in order to account for differences resulting from trial context.

Limitations to the final identified set must be considered. The study was restricted to statements and testimony identified and made available through the DATTA project (described more fully by Davis *et al*[21] in this supplement) Further, the selected statements and testimony may in part be an artefact of the search methods, particularly since some searches lent themselves to more evident results in text searches than others (for example, ''Eclipse'' versus ''Next''). Within the set of relevant documents, testimony before 1998 was quite limited, although this is to be expected given the recent availability of most PREPs. The search results were heavily weighted toward PM and RJR, and in particular, to discussion of their brands Premier, Eclipse, Accord, and Next. This may simply be a function of the early availability of these brands, or of the relative importance of these two manufacturers within the trials considered. Overall, the data provide a reasonable snapshot of testimony during the period from 1996 to 2003, but is by no means inclusive of all testimony in this area.

RESULTS

Themes and positions within testimony

A number of shared themes emerged in trials and testimony in relation to the discussion of PREPs and of new harm reduction strategies in general. These included the industry's stated commitment to its consumers and to a reduction in health risks[22–25]; the amount of time, money, and resources invested in harm reduction efforts[26–31]; the significant obstacles to development of a successful product[27 31–37]; and the continuation of industry efforts despite setbacks.[24] Failure to achieve significant harm reduction was presented not as a fault of industry efforts but rather as a problem of consumer choice.[31] For example, Dr DeBethizy, an RJR vice president of research and development (R&D), noted that the responsibility of the industry was not to make people smoke safer cigarettes, but to provide an option which would or could reduce risk if accepted by consumers: ''What we did was produced other cigarettes that people could choose to use if they wanted...''[38] Taken together, the primary role of these positions was to support the impression of having done everything possible to produce commercially acceptable reduced harm products: ''And I think we have done—taken a good faith effort to approach this. We have succeeded in some things and failed in others, but not because we hadn't tried.''[39]

Despite the many commonalities within trial testimony and statements, the review identified significant differences within each of the themes outlined above. These differences are highlighted in the sections that follow.

Comparison of PREPs to conventional cigarettes

Inevitably within a trial context, PREPs were discussed by contrast to conventional cigarettes. This contrast was sometimes highlighted or emphasised, while in other instances it was understated. In some testimony, PREPs were described as a radically different alternative to conventional cigarettes. In other testimony, PREPs were described as a new series of ''safer'' products, along the same continuum of ''safer'' products developed through gradual reduction strategies (for example, reduced ''tar'') or selective reduction strategies (for example, filtration).

An example from the ''radical change'' spectrum could be found in the following quote by Dr Townsend, a vice president of R&D for RJR (1997), when asked to describe Premier:

> I feel like Premier was a **major step forward** in addressing the smoking and health issues. It had **major reductions** in chemistry; it had **major reductions** in biology; it did have **significant reduction** in environmental tobacco smoke. **It was a very different product.** It did **perform differently** in terms of taste characteristics; it didn't burn down like a tobacco-burning cigarette. It was, in some cases, difficult to light, but I consider it a **major advance** in cigarette design.[40] [emphasis added]

Features of this statement included the use of strong declamatory phrases (''major step forward''; ''major advance'') as well as an emphasis on product differences with comparison to conventional cigarettes.

By contrast, Dr Lipowicz, a senior scientist for PM, when questioned about a similarly radical PREP concept (in this case, a battery-operated cigarette that heats rather than burns tobacco) was careful here to place the product squarely within the broader reduced harm continuum:

> Accord **is still a cigarette**. Okay. You **still heat tobacco**. You **still generate smoke** from tobacco. It **still has some of the same harmful smoke constituents** that normal cigarettes do. It **just has less** of them. **It produces smoke, but less of it**.[41] [emphasis added]

Features of this testimony were the lack of declamatory statements and an emphasis on shared characteristics with conventional cigarettes. Even the smoke from the Accord was not described as different in character from conventional smoke; instead, the emphasis was on the reduced levels of smoke (that is, similarity to ''low tar'' cigarettes).

Descriptions of commercial success and market objectives

The most obvious measures of commercial success are consumer acceptance and adoption of the new product. When discussing these measures of commercial success, the testimony varied in its evaluation of the introduction of PREPs in the market. In some cases, the term ''failure'' was applied unequivocally to describe the outcome of projects.[24 30 42] For example, Townsend acknowledged in 1997 that Premier had been a failure: ''Premier failed. Very low consumer acceptance. [Question.] And translated, was that a commercial failure? [Answer.] Definitely was a commercial failure.''[35] In other examples this type of absolute judgment was avoided in favour of a more descriptive assessment. Thus, the same witness in 2003 used consumer acceptance as the basis for evaluation, this time of the Eclipse product. However, despite a level of acceptance in the market equivalent to that of its predecessor Premier, his assessment here was more ambiguous: ''We've had a number of the [sic] acceptors of the product. I would characterize it as a very small number so far.''[43]

In other testimony, discussion of commercial market objectives bypassed measures of market performance entirely, focusing instead on the value of gathering new information. For example, Szymanczyk (CEO of PM) described the Accord test market as a ''consumer research project'', with new innovations being developed based on feedback.[44] Dr Whidby, a PM scientist, observed that because the Accord was so radically different, they ''needed to learn a lot from consumers… [for it] to have the best chance of success''.[45] Dr Lilly, vice president of R&D for PM, claimed that Accord was placed in test market to ''prove to ourselves that at least a few people would buy them'' and because ''we wanted an audience that could call us or we could call them, telling us what was wrong with them.''[37] Townsend made the same assertions regarding Eclipse in 2003.[43]

In relation to this latter market objective, testimony focused on ongoing efforts to improve PREPs in the test market,[46 47] deferring evaluation of commercial success to some time in the future rather than focusing on the present. As summarised by Ms Beasley, vice president of marketing for RJR, when asked about Eclipse in 1999: ''We're going to keep working on the product until we get it right, and I think each time we're getting closer.''[48]

Discussion of reduced harm and product safety

Although testimony was commonly in agreement that there was no such thing as a safe cigarette, a wide range of claims was made in trial regarding relative product safety. At one end of this spectrum were strong claims that significantly safer products were now available. For example, a defence attorney for RJR in 1997 cited independent testimony stating that the adoption of Premier ''will save thousands and thousands of lives'' compared to products currently being smoked.[49]

At the other end of the spectrum were statements careful to distinguish personal belief from scientific proof. Thus, in cross-examination, Dr Kassman (vice president of R&D for PM) was asked to explain an apparent reversal: ''[Question.] Haven't you testified that Accord is a safer cigarette? [Answer.] I have testified that I believe it's a safer cigarette. But I'm unable to go into the laboratory and do any testing that would be accepted or assured that the cigarette is safe.''[50] Townsend asserted that Premier was less risky than conventional cigarettes ''[i]n my heart of hearts… no question about it.''[51] A considerable amount of testimony followed this pattern.[23 33 46]

A ''strength of evidence'' approach (identified in an attorney sidebar as a new public position adopted by RJR with respect to Eclipse[52]) was also frequently cited in support of claims for a higher likelihood of product safety. DeBethizy observed that ''the weight of the evidence suggests that Accord and Eclipse are safer than conventional cigarettes.''[38] Similarly, Townsend stated that, while there is ''no scientifically-accepted protocol that allows anyone to say definitively this cigarette is safer… there's a lot of data that suggests Premier probably is.''[53]

Another quite different approach to evaluations of product safety shifted focus to the need for product acceptance and away from scientific measures. Examples included statements such as: ''[Y]ou can't have a safer cigarette unless it's something that … smokers find acceptable and will buy.''[33] ''Because having the safest product on the market is all very well; if you don't have people actually wanting to pick it up and spend money on it, that is not really going to be adding any benefits to the public health in this country.''[54] According to this line of reasoning, it would be meaningless to apply the ''reduced harm'' label to a product that no one would willingly smoke.

Conveying product benefits and claims to the consumer

The industry uniformly acknowledged in testimony the difficulty in marketing PREPs without having successfully conveyed to consumers the presumed benefits of reduced risk.[27 41 44] This point was underscored by Lipowicz:

> What we want to do is make a cigarette, make an advanced cigarette that is safer and be able to tell people that it is safer so that they might, you know, have an informed choice about smoking it. So right now we have some technologies to make cigarettes safer. We are using

> those technologies, but without the information, consumers not knowing that it's safer, you know, they wouldn't—they wouldn't know—not even know to try it. So we would like to have the ability to communicate with consumers in a direct and scientific valid manner.[41]

However, individual testimony differed considerably with regard to assessing which communications of product benefits were either possible or appropriate. DeBethizy observed that RJR could not make claims of safety without first achieving a consensus within the science and health communities.[27] Other testimony reflected the concern that explicit claims of reduced harm might result in increased liability either with respect to PREPs or to conventional products.[43] In 1999 when asked about communication of health benefits of Eclipse, Townsend replied as follows: ''[Question.] But you've never told consumers that it is safer? [Answer.]…There's no way to demonstrate that, to prove that one cigarette is safer than another.''[55]

On the other hand, testimony would continue to assert, even in the absence of a consensus within the scientific community, the right to continue making health claims. For example, Townsend in one instance defended ''making explicit health claims'' in the case of the Eclipse product (that is, that it reduces ''risk of cancer, bronchitis, and possibly emphysema''), observing that wherever reduced health risks can be ''clearly substantiated with data'', they ought to be used in advertising and marketing.[51] Likewise, DeBethizy pointed to an array of tests that had been conducted in the case of Eclipse and concluded that in the meantime, ''what we are claiming is that this cigarette presents less risk and is likely to reduce your risk based on the data that we have generated.''[27]

Contextual analysis of testimony

From the themes and statements summarised above, this section describes patterns that could provide insight into manufacturer intentions with regard to PREPs. The analysis focused particularly on differences in trial context as well as ongoing time and market changes. The relevant primary trial arguments (for example, the industry has made every effort to reduce harm; there is no feasible alternative cigarette) were widely consistent across the sample considered for this study; however, the role of PREPs in support of these arguments shifted significantly, as described below.

Legitimacy of conventional brands, despite greater health risks

Although PREPs were consistently used as an example of industry efforts to address harm reduction, their relationship to conventional cigarettes and conventional harm reduction strategies shifted. The earliest testimony contrasted conventional products with PREPs, whereas later testimony tended to promote similarities. For example, in a number of cases, earlier testimony described PREPs as ''superior'', an ''advance'' or ''different''.[40 56 57] By contrast, later testimony discussing the same or similar products tended toward more neutral terms such as ''option'', ''alternative'', or ''step in the right direction''.[30 37 38 41] Thus, in later testimony PREPs were more likely to be positioned as merely one choice (among many others) for consumers, rather than being considered as a new and significant advance—a ''better'' product—in comparison to conventional products. The distinction between PREPs and conventional brands was erased.

This shift also appeared in regard to descriptions of how PREPs were positioned in the commercial market—that is, newer PREPs were described in the market as another brand choice rather than as the ''next generation'' product (represented, for example, by Premier[40]). This point was underscored in cross-examination of Lilly:

> [Question.] And, Doctor, do you know why, why the marketing people or the people from the sky [management], do you know why they don't, with this new technology that you have worked so hard on and are working so hard on, do you know why they don't call it [Accord] like Marlboro Two, the next generation, or Marlboro Two, the new generation? Do you know why they don't do that? [Answer.] I can't give you why. I don't sit in on marketing meetings. We have discussed in the research group the same thing you are asking me.[58]

Different standards for evaluating reduced harm versus conventional brands

In contrast to the similarities drawn between conventional and non-conventional harm reduction strategies, the testimony consistently differentiated standards that were appropriate for evaluating and communicating relative health risks of conventional cigarettes versus PREPs. For example, Townsend argued that industry measures of harm were sufficient to evaluate PREPs.[51] Yet he claimed that larger epidemiological studies would be required to evaluate conventional brands, asserting that ''[t]he basis for concluding that low tar is less risky is, in fact, epidemiology'' and that it was the role of the public health community to conduct that kind of research.[51] Likewise Whidby acknowledged that, in contrast to its evaluation of PREPs, the industry had not ''marshal[led] that evidence with regards to biological safety or reduced risks'' with its introduction of ''low tar'' offerings such as Cambridge.[59] This distinction was a focus of plaintiff's attorneys in cross examination, as it raised questions with regard to the validity of health claims for PREPs in the absence of epidemiology and large-scale public health studies,[59] while at the same time undermining the legitimacy of conventional harm reduction efforts (that is, gradual reduction, selective filtration, etc).[32]

Need for product claims sufficient to promote reduced harm products

The government and public health community were commonly paired as the main opposition to the introduction of safer products.[24 49] For example, the government was described as preventing dissemination of information to the consumer regarding product safety.[29] As DeBethizy observed with regard to the introduction of Premier: ''People [public health officials] came out and did all kinds of bizarre things to try to discredit this product. And it was really unfortunate because it was the crown jewel of efforts and of our efforts, and it really reduced the toxicity dramatically.''[27]

However, as earlier, dramatic claims boasting the development of safer products gradually gave way to increasing caution, the testimony showed less concern with government and public health opposition to new products, and more concern with how to legitimise claims of product safety. Later testimony focused on which measures of safety were available, and on what they were able to measure. DeBethizy described a ''battery of assays'' used to support the argument that ''in a variety of different ways you have reduced toxicity''. Reduction must be measured separately ''at the cellular level, at the DNA level, at the chromosome level, at the skin intact organ level, in the variety of portions of the airway, and in every other tissue in the body.''[27] In later testimony, the intent to *prove* increased product safety with regard to PREPs was abandoned. Instead, increased product safety was *implied* through the discussion of favourable

results from any number of individual (but inconclusive) measures. For example, as summarised by Dr Lewis, vice president of R&D for PM:

> We know that exposure is way down in this product. We know that the chemistry is good. We know exposures that we measure in humans is way down, but we don't know enough about the specific mechanism of what causes disease to say that this product doesn't still have what it takes to cause disease.[47]

Taking the place of direct assertions of reduced risk was a growing call for third party review and validation of health claims. For example, testimony by DeBethizy and others singled out the efforts by IOM to develop guidelines for PREP evaluation, noting: ''they've described a way that you can put the evidence together and have it reviewed by an independent body of scientists and they would look at it and see whether you had the expectation or the anticipation that it would be safer.''[27 41 44] Independent validation of health claims would enable the industry to market PREPs to consumers in the absence of direct measures for product safety.

Progress of industry efforts toward harm reduction

Testimony consistently supported the impression of progress toward harm reduction, despite the reality of repeated setbacks and the failure of PREPs to have demonstrated any signs of commercial acceptance in test market.[43 47 58] The fact that PREPs had not achieved market success was obscured behind the conviction that significant commercial progress was likely to be achieved at any moment. It was commonly accepted, as for example by Lilly in 2001 with regard to Accord, that ''the technology is ready now''.[37] Although in practice, PREPs often remain in test market for many years without being introduced nationally, in testimony, this reality was rarely if ever reflected. New and safer technologies were claimed to be commercially ready, while test markets were represented as a transitory step toward the commercial goal.

Promises with regard to commercial introduction—and by extension, commercial acceptance—of PREPs became especially remarkable as they were forestalled from one year's testimony to the next. A specific time frame for new product introductions was indicated in testimony for a number of different PREP brands (including Eclipse, Accord, and SCoR) all of which failed to come to fruition.[37 41 60 61] Yet, further new market introductions and the probability of success were always described as just around the corner. Indeed, the single exception was quite refreshing: in 2003, Dr Gentry, a vice president of R&D for RJR, observed when pressed on the issue that, based on ''the evidence and what we've seen in test marketing so far… certainly Eclipse is not doing well in the markets that it's doing in. I hope that it does well, um, but having been through Premier and Eclipse now, high hopes is not something I've got.''[61]

DISCUSSION

The primary role of tobacco industry discussion of PREPs in trial testimony is to provide an effective defence in litigation. By emphasising efforts to develop safer products, the trial testimony supported industry claims that they acted to reduce harm, despite the failure of PREPs in the marketplace. At the same time, by focusing on lack of consumer acceptance, the industry absolved itself of responsibility for the marketing and adoption of these products. Thus, PREP development was used to convey that, while the industry has not yet achieved success in harm reduction, it has acted in good faith.

What this paper adds

The potential impact of potential reduced exposure products (PREPs) and other new products promising reduced health risks has made them the subject of considerable debate within the tobacco control community and an emerging research priority among government and health agencies. However, the lack of publicly available information with regard to reduced harm products has made comprehensive evaluation difficult.

This is the first study to assess tobacco trial testimony as a means to gain insight into industry strategies and intentions regarding reduced harm products. Findings suggest that the industry position has shifted since PREPs were initially introduced to the market, with promotion of ''breakthrough'' products increasingly tempered by market failures and the need to protect the conventional cigarette market. Findings further suggest that the industry is unlikely to pursue an aggressive strategy of reduced harm without government intervention or independent validation of proposed health claims.

Although testimony is likely to reflect the ongoing development of trial strategy, as much as if not more so than to reflect developments in the external market or in broader company strategy, there are indications that the evolution of testimony may provide insight into industry intentions with regard to PREPs. This insight, viewed in combination with other relevant sources of information regarding industry strategies, could be of value with regard to future evaluation and regulation of reduced harm products. For example, earlier testimony was consistent with a greater expectation of eventual consumer adoption of PREPs and gradual market success for one or more potential breakthrough technologies. However, perhaps as failures in the market tempered this initial enthusiasm, the focus shifted to how not to kill the golden goose (conventional cigarettes), despite the acknowledgment of new technologies that presented safer alternatives.

Thus, over the span of trial testimony there appears to have been a strategic repositioning in which PREPs became increasingly placed within a broader continuum as one more choice for consumers to consider. This shift legitimised the sale of conventional brands, and reinforced the transfer of responsibility for adoption of safer products from the manufacturer to the consumer, thereby protecting the traditional cigarette market. Indeed, within this framework, nothing prevents the industry from continuing to introduce new products with higher tar deliveries, at the same time as they are introducing lower tar and reduced-risk brands.

As PREPs can only represent a viable ''choice'' for consumers for as long as they remain in market, it comes as no surprise that in practice PREPs frequently remain in test market indefinitely, despite no indication of market progress. In the face of continued commercial failure, trial testimony has remodelled test markets into ongoing consumer research projects, with ''success'' defined in terms of information gathering rather than consumer acceptance. This shift justifies the continuation of these test markets in spite of a lack of progress by any traditional measure. At the same time, the promise of imminent product acceptance is directly implied within testimony, reinforcing the good faith position of the industry.

The findings outlined in trial testimony illustrate the major dilemma presented by the introduction of PREPs as a viable

long-term strategy. Early dramatic PREP health claims undermined the legitimacy of the industry's efforts to reduce harm in conventional products, and indeed the legitimacy of conventional products more generally. Yet, without the ability to make health claims, the industry will remain unable to market PREPs or present product benefits to consumers, eliminating PREPs as a viable commercial opportunity (and weakening evidence of their efforts toward pursuit of harm reduction). An initial response within testimony to this dilemma was the practice of implying health claims through discussion of favourable results from individual measures. This practice has in fact been used publicly in the marketing of new products such as Eclipse and Omni. However, such claims have proven to be open to regulatory challenges and litigation. A long-term solution advocated in more recent testimony was the broad acceptance of independent guidelines that would validate use of health claims and enable the industry to market PREPs to consumers.

Overall, the evidence from trial statements suggests that the industry's primary intention is to protect its conventional products, with only marginal support of PREPs so long as health claims remain impractical and commercial adoption continues to appear unrealistic. Thus, the industry would seem unlikely to pursue an aggressive strategy of reduced harm without government intervention or independent validation to support the explicit use of health claims and encourage wide-scale consumer adoption.

ACKNOWLEDGEMENTS

This work was supported by grants from the National Cancer Institute (CA087486) and the American Legacy Foundation (6211) to the Michigan Public Health Institute, Center for Tobacco Use Prevention and Research (Okemos, Michigan, USA). The views expressed in this paper do not necessarily represent those of the National Cancer Institute, the American Legacy Foundation, or the Foundation's staff or Board of Directors.

Competing interests: none declared

GFW is affiliated to Harvard School of Public Health

REFERENCES

1 **Gori GB**. Low-risk cigarettes: a prescription. *Science* 1979;**194**:1243–6.
2 **Wynder E**, Hoffmann D. Tobacco and health: a societal challenge. *N Engl J Med* 1979;**300**:894.
3 **US Department of Health, Education, and Welfare**. *Smoking and health. Report of the Advisory Committee to the Surgeon General of the Public Health Service*. Washington, DC: Public Health Service, 1964, (PHS Publication No. 1103).
4 **Hoffmann D**, Hoffmann I. The changing cigarette, 1950–1995. *J Toxicol Environ Health* 1997;**50**:307–64.
5 **US Department of Health and Human Services**. *Reducing tobacco use: a report of the surgeon general—executive summary*, US Department of Health and Human Services. Centers for Disease Control and Prevention. Office on Smoking and Health, 2000.
6 **Kozlowski LT**, Pillitteri JL. Beliefs about ''Light'' and ''Ultra Light'' cigarettes and efforts to change those beliefs: an overview of early efforts and published research. *Tob Control* 2001;**10**(suppl I):i12–6.
7 **US Department of Health and Human Services**. *Smoking and Tobacco Control Monograph 13: risks associated with smoking cigarettes with low tar machine-measured yields of tar and nicotine*, US Department of Health and Human Services. Public Health Service. National Institutes of Health. National Cancer Institute, October, 2001.
8 **Thun MJ**, Burns DM. Health impact of ''reduced yield'' cigarettes: a critical assessment of the epidemiological evidence. *Tob Control* 2001;**10**(suppl I):i4–11.
9 **Pollay RW**, Dewhirst T. The dark side of marketing seemingly ''Light'' cigarettes: successful images and failed fact. *Tob Control* 2002;**11**(suppl I)i18–31.
10 **Cummings K**, Morley C, Hyland A. Failed promises of the cigarette industry and its effect on consumer misperceptions about the health risks of smoking. *Tob Control* 2002;**11**(suppl I):i110–17.
11 **Kozlowski L**, O'Connor R. Cigarette filter ventilation is a defective design because of misleading taste, bigger puffs, and blocked vents. *Tob Control* 2002;**11**(suppl I)i40–50.
12 **Leavell N**. The low tar lie. *Tob Control* 1999;**8**:433–9.
13 **World Health Organization, SACTob (Scientific Advisory Committee on Tobacco regulation)**. Statement of principles guiding the evaluation of new or modified tobacco products. Geneva: WHO, 2003.
14 **DeBethizy JD**, Borgerding MF, Doolittle DJ, *et al*. Chemical and biological studies of a cigarette that heats rather than burns tobacco. *J Clin Pharmacol* 1990;**30**:755–63.
15 **Meckley DR**, Hayes JR, Van Kampen KR, *et al*. Comparative study of smoke condensates from 1R4F cigarettes that burn tobacco versus ECLIPSE cigarettes that primarily heat tobacco in the SENCAR mouse dermal tumor promotion assay. *Food Chem Toxicol* 2004;**42**:851–63.
16 **Eclipse Cigarettes Official Website**. http://www.eclipse.rjrt.com/ (accessed 8/15/2004); Summary of Scientific Tests Regarding Tobacco heating Eclipse Cigarette: http://www.eclipsescience.com/ (Accessed 15 Aug 2004).
17 **Weiss R**. RJR to heavily market new cigarette. *Washington Post*. 19 April, 2000.
18 **Slade J**, Connolly GN, Lymperis D. Eclipse: does it live up to its health claims? *Tob Control* 2002;**11**(suppl II):ii64–70.
19 **Stratton KS**, Wallace R, Bondurant S, eds. *Clearing the smoke: assessing the science base for tobacco harm reduction*. Washington, DC: National Academy Press, 2001.
20 **Shiffman S**, Pillitteri JL, Burton SL, *et al*. Smoker and ex-smoker reactions to cigarettes claiming reduced risk. *Tob Control* 2004;**13**:78–84.
21 **Davis M**, Douglas CE, Beasley JK. The Tobacco Deposition and Trial Testimony Archive (DATTA) project: origins, aims, and methods. *Tob Control* 2006;**15**(suppl IV):iv4–8.
22 **David JM**. (R.J. Reynolds Tobacco Co.). Closing statement. Nunnally v. R.J. Reynolds Tobacco Co. & Basic Foods, Inc. July 11, 2000. 2623–2636. http://tobaccodocuments.org/datta/PCSNUNNALLY071100.html.
23 **Whidby JF**. Trial testimony. Mehlman v. Philip Morris, Inc. April 26, 2001. 3019–3032. http://tobaccodocuments.org/datta/TOWNSENDD042601.html.
24 **Gentry JS**. Trial testimony. Allen v. Philip Morris, Inc. February 20, 2003. 0057–0073. http://tobaccodocuments.org/datta/GENTRYJ022003.html.
25 **Crist PG**. (R.J. Reynolds Tobacco Co.). Closing statement. Raulerson [Connor] v. R.J. Reynolds Tobacco Co. May 2, 1997. 5153–5155. http://tobaccodocuments.org/datta/DCSCONNOR050297PM.html.
26 **Whidby JF**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. October 30, 2001. 4763–4832. http://tobaccodocuments.org/datta/WHIDBYJ103001AM.html.
27 **DeBethizy JD**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. October 31, 2001. 5146–5219. http://tobaccodocuments.org/datta/DEBETHIZYJ103101.html.
28 **Kassmann A**. Trial testimony. Allen v. Philip Morris, Inc. February 20, 2003. 0186–0207. http://tobaccodocuments.org/datta/GENTRYJ022003.html.
29 **Townsend DE**. Trial testimony. Anderson v. American Tobacco Co. June 1, 2000. 4791–4866. http://tobaccodocuments.org/datta/TOWNSENDD060100.html.
30 **Whidby JF**. Trial testimony. Boeken v. Philip Morris, Inc. May 14, 2001. 5560–5578. http://tobaccodocuments.org/datta/WHIDBYJ051401.html.
31 **Whidby JF**. Trial testimony. Bullock v. Philip Morris, Inc. September 13, 2002. 3317–3445. http://tobaccodocuments.org/datta/BIBLEG091302.html.
32 **DeBethizy JD**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. October 31, 2001. 5221–5290. http://tobaccodocuments.org/datta/DEBETHIZYJ103101.html.
33 **Lipowicz PJ**. Trial testimony. Eastman v. Brown & Williamson. March 31, 2003. 3768–3810. http://tobaccodocuments.org/datta/LIPOWICZP033103.html.
34 **Townsend DE**. Trial testimony. Rogers v. R.J. Reynolds Tobacco. August 15, 1996. 1725–1730. http://tobaccodocuments.org/datta/TOWNSENDD081596.html.
35 **Townsend DE**. Trial testimony. Broin v. Philip Morris Inc. September 29, 1997. 15330–15333. http://tobaccodocuments.org/datta/TOWNSENDD092997.html.
36 **Carchman RA**. Trial testimony. Butler v. Philip Morris Inc. May 27, 1999. 3831–3836. http://tobaccodocuments.org/datta/CARCHMANR052799PM.html.
37 **Lilly AC**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. November 5, 2001. 5639–5687. http://tobaccodocuments.org/datta/LILLYA110501.html.
38 **DeBethizy JD**. Trial testimony. Whiteley v. Raybestos-Manhattan Inc. February 22, 2000. 3830–3848. http://tobaccodocuments.org/datta/DEBETHIZYJ022200.html.
39 **Carchman RA**. Trial testimony. Williams v. Philip Morris Inc. March 16, 1999. 89–99. http://tobaccodocuments.org/datta/CARCHMANR031699PM.html.
40 **Townsend DE**. Trial testimony. Raulerson [Connor] v. R.J. Reynolds Tobacco Co. April 24, 1997. 3332–3367. http://tobaccodocuments.org/datta/TOWNSENDD042497.html.
41 **Lipowicz PJ**. Trial testimony. Eastman v. Brown & Williamson. March 31, 2003. 3810–3851. http://tobaccodocuments.org/datta/LIPOWICZP033103.p31-40.html.
42 **Beasley LJ**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. May 13, 1999. 11–18. http://tobaccodocuments.org/datta/BEASLEYL051399PM.html.
43 **Townsend DE**. Trial testimony. Lucier v. R.J. Reynolds Tobacco Co. January 10, 2003. 8258–8271. http://tobaccodocuments.org/datta/TOWNSEND011003AM2.html.
44 **Szymanczyk M**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. June 14, 2000. 54154–54156. http://tobaccodocuments.org/datta/SZYMANCZYKM061400PM.html.
45 **Whidby JF**. Trial testimony. Bullock v. Philip Morris, Inc. September 17, 2002. 3448–3471. http://tobaccodocuments.org/datta/BULLOCKB091702.html.

46 **Townsend DE**. Trial testimony. Kenyon v. R.J. Reynolds Tobacco Co. November 29, 2001. 2476–2487. http://tobaccodocuments.org/datta/VANDYK112901.html.
47 **Lewis J**. Trial testimony. Reller v. Philip Morris, Inc. July 15, 2003. 9372–9398. http://tobaccodocuments.org/datta/LEWISJ071503PM.html.
48 **Beasley LJ**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. May 13, 1999. 18–26. http://tobaccodocuments.org/datta/BEASLEYL051399PM.html.
49 **Grossman TM**. Closing statement. Karbiwnyk v. R.J. Reynolds Tobacco Co. October 27, 1997. 4324–4331. http://tobaccodocuments.org/datta/DCSKARBIWNYK102997PM.html.
50 **Kassman A**. Trial testimony. Reller v. Philip Morris, Inc. July 15, 2003. 9309–9311. http://tobaccodocuments.org/datta/KASSMANA071503.html.
51 **Townsend DE**. Trial testimony. Nunnally v. R.J. Reynolds Tobacco Co. July 6, 2000. 1879–1888. http://tobaccodocuments.org/datta/FISCHERJ070600.html.
52 **Reid R**. Benjamine. (R.J. Reynolds Tobacco Co.). Sidebar discussion. Engle v. R.J. Reynolds Tobacco Co. June 21, 2000. 44–53. http://tobaccodocuments.org/datta/DEBETHIZYJ062100AM.html.
53 **Townsend DE**. Trial testimony. Mehlman v. Philip Morris, Inc. April 26, 2001. 2880–2907. http://tobaccodocuments.org/datta/TOWNSENDD042601.html.
54 **Brookes NG**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. June 15, 2000. 7–14. http://tobaccodocuments.org/datta/BROOKESN061500PM.html.
55 **Townsend DE**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. March 4, 1999. 26150–26168. http://tobaccodocuments.org/datta/TOWNSENDD030499.html.
56 **Townsend DE**. Trial testimony. Engle v. R.J. Reynolds Tobacco Co. March 2, 1999. 25679–25715. http://tobaccodocuments.org/datta/TOWNSENDD030299AM.html.
57 **Reynolds ML**. Trial testimony. Widdick [Maddox] v. Brown & Williamson Tobacco Co. June 2, 1998. 4924–4933. http://tobaccodocuments.org/datta/REYNOLDSM060298.html.
58 **Lilly AC**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. November 5, 2001. 5687–5700. http://tobaccodocuments.org/datta/LILLYA110501.html.
59 **Whidby JF**. Trial testimony. Tobacco Litigation (Medical Monitoring Cases) [Blankenship]. October 30, 2001. 4857–4876. http://tobaccodocuments.org/datta/WHIDBYJ103001AM.html.
60 **Whidby JF**. Trial testimony. Boeken v. Philip Morris, Inc. May 14, 2001. 5471–5499. http://tobaccodocuments.org/datta/WHIDBYJ051401.html.
61 **Gentry JS**. Trial testimony. Allen v. Philip Morris, Inc. February 20, 2003. 0092–0129. http://tobaccodocuments.org/datta/GENTRYJ022003.html.